K033618

FEB - 5 2004

ATTACHMENT III: REVISED 510(k) SUMMARY

Revised 510(k) Summary:

Sponsor:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Contact: Bonnie Smith

Device Name: Synthes (USA) Retrograde/Antegrade Femoral Nail System

Device Classification:
21 CFR 888.3020 – "Intramedullary fixation rod"
21 CFR 888.3040 – "Smooth or threaded metallic bone fixation fastener"

Predicate Device: Synthes Distal Femoral Nail, Synthes Cannulated Femoral Nail, and DePuy ACE ART Femoral Nail.

Description of Device: Synthes Retrograde/Antegrade Femoral Nail System is composed of femoral nails, spiral blades and end caps. Depending on the length of the nail, the nail may be inserted from a retrograde approach or from either a retrograde or antegrade approach. Spiral blades, end caps and Synthes commercially available locking bolts and screws are used to secure the nail in the bone, preventing rotation and axial compression.

Indications: Synthes Retrograde/Antegrade Femoral Nail System is intended to stabilize fractures of the distal femur and the femoral shaft, including supracondylar fractures, including those with intra-articular extension; ipsilateral hip/shaft fractures; ipsilateral femur/tibia fractures; femoral fractures in multiple trauma patients; fractures proximal to total knee arthroplasty; fractures distal to a hip implant; fractures in the morbidly obese; fractures in osteoporotic bone, impending pathologic fractures; and malunions and nonunions.

Material: Titanium alloy

Substantial Equivalence: Documentation is provided which demonstrates that the Synthes Retrograde/Antegrade Femoral Nail System is substantially equivalent* to other legally marketed devices.

* The term "substantially equivalent" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matter. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2004

Ms. Bonnie J. Smith
Senior Regulatory Affairs Associate
Synthes (USA)
1690 Russell Road
P.O. Box 1766
Paoli, Pennsylvania 19301

Re: K033618
Trade/Device Name: Synthes (USA) Retrograde/Antegrade Femoral Nail System
Regulation Numbers: 21 CFR 888.3020 and 888.3040
Regulation Names: Intramedullary fixation rod and Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: HSB, HWC
Dated: November 17, 2003
Received: November 18, 2003

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT II: REVISED INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K033618

Device Name: Synthes (USA) Retrograde/Antegrade Femoral Nail System

Indications for Use:

Synthes Retrograde/Antegrade Femoral Nail System is intended to stabilize fractures of the distal femur and the femoral shaft, including:

- supracondylar fractures, including those with intra-articular extension
- ipsilateral hip/shaft fractures
- ipsilateral femur/tibia fractures
- femoral fractures in multiple trauma patients
- fractures proximal to total knee arthroplasty
- fractures distal to a hip implant
- fractures in the morbidly obese
- fractures in osteoporotic bone
- impending pathologic fractures
- malunions and nonunions

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

for Mark N Milkerson

K033618